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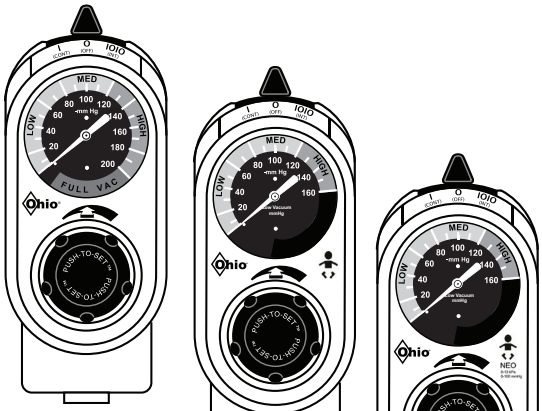
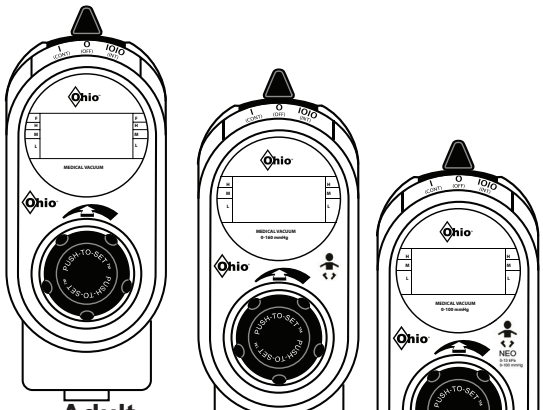
Vacuum Regulator, Push-To-Set™ Intermittent Suction Unit (PTS-ISU)

Service Manual

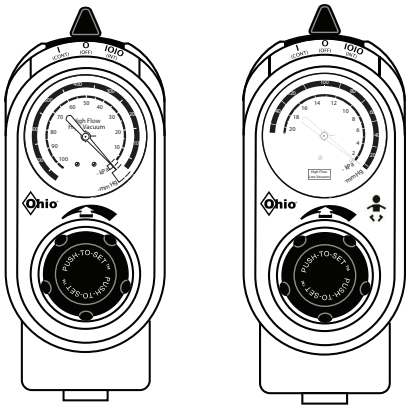
Adult, Pediatric and Neonatal



PTS-ISU - Analog
ANSI



PTS-ISU - Digital
ANSI/ISO



PTS-ISU - Analog
ISO

℞ ONLY

8700-0001-000 Rev. 10 (05/2015)

User Responsibility

This Product will perform as described in this operating manual and accompanying labels and/or inserts, when assembled, operated, maintained and repaired in accordance with the instructions provided. This Product must be checked periodically. A defective product should not be used. Parts that are broken, missing, worn, distorted or contaminated should be replaced immediately. For service advice, Ohio Medical recommends that a telephone request be made to the nearest Ohio Medical Regional Service Center. This product and any of its parts should only be repaired using written instructions provided by Ohio Medical or by Ohio Medical trained personnel. The Product must not be altered without the prior written approval of Ohio Medical's Quality Assurance Department. The user of this Product shall have the sole responsibility for any malfunction which results from improper use, faulty maintenance, improper repair, damage, or alteration by anyone other than Ohio Medical.

AAA A 12345 This alpha character indicates the year of product manufacture and when the serial number was assigned; "L" = 2007, "M" = 2008, "N" = 2009, etc. "I" and "O" are not used.

Safety Instructions

This manual provides you with important information about the Push-To-Set™ Intermittent Suction Unit (PTS-ISU). To ensure the safe and proper use of this device, READ and UNDERSTAND all of the safety and operating instructions. IF YOU DO NOT UNDERSTAND THESE INSTRUCTIONS, OR HAVE ANY QUESTIONS, CONTACT YOUR SUPERVISOR, DEALER OR THE MANUFACTURER BEFORE ATTEMPTING TO USE THE DEVICE.

Intended Use

The vacuum regulator is intended to be used in the medical facility as a means to evacuate media (i.e. fluids) from the body. DO NOT use this vacuum regulator for anything other than its intended use.

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1.1 Definition

WARNING = possible injury to patient or operator

CAUTION = possible damage to equipment

Note = Provides additional information to clarify a point in the text.

Important = Similar to a note but of greater emphasis

|O|O (INT) = Intermittent (ON/OFF)

| (CONT) = Continuous (ON)

O (OFF) = OFF

⚠ **Consult Instructions for Use**

SN **Serial Number**

Manufacturer

Abbreviations Used in the Manual

CCW	Counter-clockwise (decrease)
CW	Clockwise (increase)
Eto	Ethylene oxide
inHg	Inches of mercury
in	Inch
ISU	Intermittent Suction Unit
IFU	Instructions for Use
kPa	Kilopascals (kPa x 7.50 = 1 mmHg)
LPM	Millimeters of mercury (mmHg x .133 = kPa)
mmHg	Liters per minute
mm	Millimeters
mL	Milliliters
oz	Ounces
°C	Degrees Celsius
°F	Degrees Fahrenheit
N-m	Newton-Meter (N-m x .737 = ft-lb)
ft-lb	Foot-Pound Force (ft-lb x 1.356 = N-m)
in-lb	Inch-Pound Force (ft-lb x 12 = in-lb)
DISS	Diameter Index Safety System
OES	Oxequip® Suction
OST	Overflow Safety Trap
NCG	National Compressed Gases
BOC	British Oxygen Corporation
NEO	Neonatal
NFPA	National Fire Protection Association
NPT	National Pipe Thread (USA)
MPTS	Multi-Purpose Therapy Stand
ID	Inner Diameter
gal	gallon
PED	Pediatric
PTS	Push-To-Set™
PTFE	Polytetrafluoroethylene
NG	Nasogastric
RH	Relative Humidity

1.2 WARNINGS

Factory settings may be impacted during transport therefore, the unit's timing cycle should be checked prior to initial use and adjusted if necessary (see Section 7.6 Timing Cycle Adjustment).

This device should be repaired only by qualified Ohio Medical or Ohio Medical-trained, qualified personnel, using only Ohio Medical recommended parts. There are risks associated with using anything other than Ohio Medical parts. Ohio Medical will assume no responsibility for incidents which may occur if the product was not repaired in accordance with procedures authorized by Ohio Medical.

If the vacuum regulator is repaired or disassembled in any manner, the service checkout procedure must be performed before using the equipment on a patient.

After patient use, if regulator is contaminated then handle in accordance with you hospital's infection control policy.

To reduce transportation personnel and/or service personnel exposure to hazardous contamination, DO NOT ship any suction equipment that has been contaminated.

Do not use this device in the presence of flammable anesthetics. Static charges may not dissipate and a possible explosion hazard exists in the presence of these agents.

Connection to positive pressure sources such as oxygen and medical air, even momentarily, could injure the patient or operator.

Ohio Medical will assume no responsibility for incidents which may occur if the product is not used in accordance with product labeling.

To help prevent aspirate from entering the device, wall outlet and pipeline equipment, a safety trap should be attached prior to its use. Aspirate in the regulator, wall outlet and pipeline equipment may impair its operations. The use of the safety trap and suction filter will help prevent this and extend the life of suction equipment.

1.3 CAUTION

Do not use any Loctite® products or any products which contain Methacrylate Ester as an active ingredient to seal the threads on the adapters/ probes and fittings.

Use of lubricants other than recommended may degrade plastic or rubber components.

Do not steam autoclave or liquid sterilize the regulator. Severe impairment to the operation of the regulator will result. The only acceptable method of sterilization is with gas (ethylene oxide).

Sterilization with ethylene oxide mixtures may cause crazing (minute superficial cracking) of some plastic parts. Crazing will be more pronounced when mixtures containing Freon® are used.

Following sterilization with ethylene oxide, parts should be quarantined in a well ventilated area to allow dissipation of residual ethylene oxide gas absorbed by the material. Aerate parts for 8 hours at 54°C (130°F). Follow your hospital sterilization procedure.

Do not use harsh chemical or cleaning solution. Do not spray cleaners directly onto suction regulators. Only use chemical recommended in this manual.

If any evidence of damage is found, repair as necessary or contact your authorized service provider.

Connection to **positive** pressure sources **such as oxygen and medical air,** even momentarily, could damage the equipment.

The suction control knob must be completely pushed in to adjust the vacuum level. Failure to do so may damage the vacuum regulator.

Not for transport use: The categories of field and transport user are specifically defined in ISO 10079-3. "Field" means use at accidents or emergencies outside a hospital. "Transport" means use in ambulances, cars and airplanes. These situations may expose the equipment to uneven support, water, dirt, and mechanical shock and temperature extremes. Ohio Medical Suction equipment has not been tested to comply with the specific requirements of these categories.

Note: Ohio Medical requests that parties acquiring this device:

Report the device's purchase, receipt in trade, return after sale, loss, destruction, or retirement.

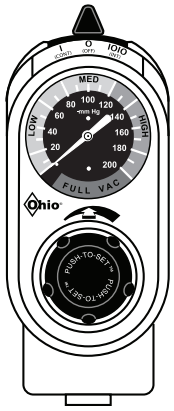
Contact your Ohio Medical customer service representative to obtain manual updates.

Authorized Service Center / Customer Service
Call 1-866-549-6446 or +1 847-855-0500 for service and repair information.

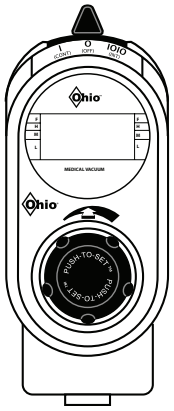
This service manual contains service, maintenance and parts information for the Push-To-Set™ Adult, Pediatric and Neonatal Intermittent Suction Unit (PTS-ISU)

2.1 ANSI Vacuum Regulator (Analog/Digital)

Note: Part numbers given are for Vacuum Regulators without fittings or adapters/probes.



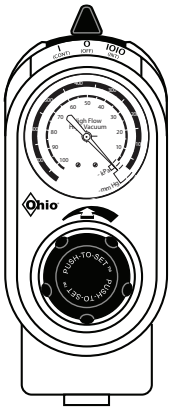
PTS-ISU
8700-XXXX-900
Adult: 1251
Pediatric: 1271
Neonatal: 1279



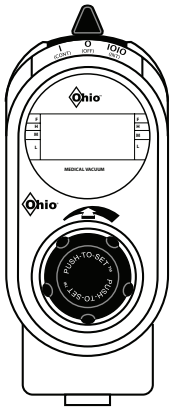
PTS-ISU Digital
8700-XXXX-900
Adult: 1351
Pediatric: 1371
Neonatal:1372

2.2 ISO Vacuum Regulator (Analog/Digital)

Note: Part numbers given are for Vacuum Regulators without fittings or adapters/probes.



PTS-ISU
8700-XXXX-900
Adult: 1253
Pediatric: 1273



PTS-ISU Digital
8700-XXXX-900
Adult:1353
Pediatric: 6373
Neonatal: 6372

Figure 1

3.1 Description

A patented safety feature Push-To-Set™ (PTS) automatically occludes the patient circuit as the desired vacuum level is selected. It prevents higher than desired vacuum levels from being accidentally delivered when patient suctioning begins. The suction control knob must first be pushed and then turned to set vacuum levels.

Each unit contains a dual spring regulator module to regulate and adjust suction which is precise in the critical care range; Adult: 0-200 mmHg (0-26.7 kPa); Pediatric: 0-135 mmHg (0-18.0 kPa); Neonatal: 0-100 mmHg (0-13.3 kPa) and quickly moves to full wall vacuum for resuscitation. It requires only two turns from zero to full wall vacuum. Each unit contains a vacuum gauge, an ON/OFF switching module and adjustable timing valves.

In use, the vacuum source is connected through the regulator module which functions as an automatic valve. Rotating the suction control knob adjusts the position of the regulator module and selects a predetermined level of suction.

During use, as the flow requirement increases, the valve automatically opens to maintain suction at the preset level. Conversely, when the flow requirement decreases, the valve automatically closes to maintain suction at the preset level. The same mechanism compensates for changes in supply vacuum to automatically maintain the pre-set suction level.

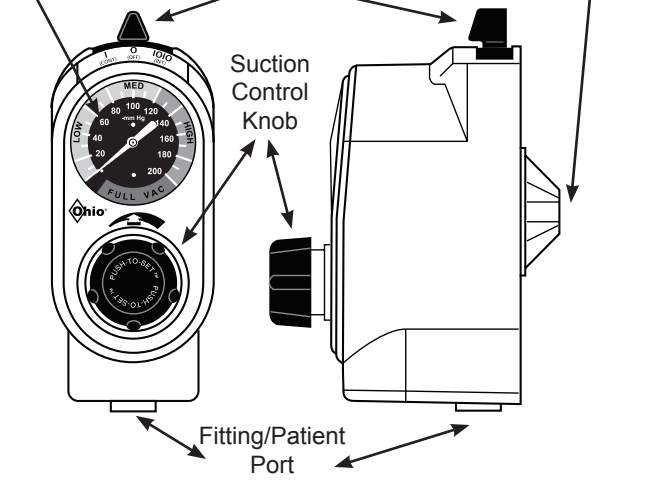


Figure 2: Front and Side View

3.2 Specifications

TECHNICAL SPECIFICATIONS

Performance				
		Adult	**Pediatric**	**Neonatal**
Flow rate	Intermittent	8 LPM	8 LPM	8 LPM
	Continuous	80 LPM[3]	80 LPM[3]	80 LPM[3]
		0-16 LPM (Preset at 8 LPM)		
Timing	15 seconds ON, 8 seconds OFF (± 3 seconds) Can be adjustable Starts in the ON cycle			
Positive Pressure Safety Relief Valve:	Located in the vacuum supply line to prevent pressurization of the patient connection by failed injector vacuum (Venturi) units, or inadvertent cross connection to pressured gases.			
Gauge Accuracy		**Analog[1]**		**Digital[2]**
Adult	0-200 mmHg (0-26.7 KPA)	±5% Full-scale		±1% Full-scale
Pediatric	0-160 mmHg (0-21.3 KPA)	±5% Full-scale		±1% Full-scale
Neonatal	0-160 mmHg (0-21.3 KPA) 0-100 mmHg (0-13.3 KPA)	±5% Full-scale ±5% Full-scale		±1% Full-scale ±1% Full-scale
Physical				
Dimensions	6.5”H x 2.8”W x 4.8”D (16.5 cm x 7.1 cm x 12.2 cm)			
Weight	20 oz (567 grams)			
Battery				
Lithium	Two 2/3 AA batteries, 3.6V, 1.6 Ah, lithium			

[1]full scale deflection
[2]full range at 22°C
[3]not adjustable, without fittings at full increase

ENVIRONMENTAL SPECIFICATIONS

Operating Temperature Range	**50 to 104ºF (10 to 40ºC)**
Storage Temperature Range	**-13 to 158ºF (-25 to 70ºC)**
Operating and storage Relative Humidity	**5 to 95% RH (Non-condensing)**
Ingress Protection Ratings:	**IP 20**

4.1 Cleaning and Disinfection

WARNING: After patient use, regulators may be contaminated. Handle in accordance with your hospital's infection control policy.

CAUTION: Suctioned fluids drawn into a vacuum regulator do not stop in the regulator. They proceed through it into the wall outlet and pipeline system. Failure to clean and disinfect the wall outlet and pipeline system may result in damage to this equipment.

4.1.1 Routine Exterior Cleaning

Routine cleaning of the regulator is recommended as a standard procedure after each use. Wipe all exterior surfaces with a solution of water and mild detergent and/or an approved cleaning solution.

4.1.1.1 Approved Cleaning Solutions

- Sodium Hypochlorite 0.5% (Bleach): Mixture of 13 fl. oz. of bleach to 1 gallon (128 fl. oz.) tap water
- Isopropyl Alcohol 70%
- Hydrogen Peroxide 3%
- Cavicide® Ready to use full strength

4.2 Sterilization

Should misuse occur, resulting in accidental flooding of the regulator, the regulator may be sterilized using Ethylene oxide (ETO). After sterilization, follow the service checkout procedures (Section 7 Service Checkout Procedure).

WARNING: Following sterilization with ethylene oxide, parts should be quarantined in a well ventilated area to allow dissipation of residual ethylene oxide gas absorbed by the material. Aerate parts for 8 hours at 130°F (54°C). Follow your hospital sterilization procedure.

CAUTION: Do not steam autoclave or liquid sterilize the intermittent vacuum regulator. Severe impairment to the operation of the regulator will result. The only acceptable method of sterilization is with gas (ethylene oxide).

CAUTION: Sterilization with ethylene oxide mixtures may cause crazing (minute superficial cracking) of some plastic parts. Crazing will be more pronounced when mixtures containing Freon® are used.

Note: The vacuum regulator should only be sterilized if it is contaminated or maintenance is to be performed.

SYMPTOM	POSSIBLE CAUSES	POSSIBLE SOLUTION
Unit fails to provide vacuum at patient port in all modes.	Mode Selector Switch is at O(OFF) position	Move mode selector switch [34] to desired mode.
	Mode Selector Switch is at |O|O(INT) mode and unit stays in the OFF cycle.	Adjust/Replace Timing Module Assembly [24]
	No Supply Vacuum	Check Hospital vacuum level (should be at least 500 mmHg (66.7 KPA).
	Damaged/Clogged Supply side or Patient side fittings	Replace fittings if damaged/clogged Retighten/Torque if found loose
	Knob fails to return when pushed	Push and rotate the knob [3] if stuck Replace actuator [10], drive gear [7], Regulator Case [6], OTS assembly [11].
	Knob stuck at OFF position (all the way counter clock direction)	Push and Rotate Knob [3] to clock wise direction
	Damaged Regulator Module	Regulator Module Assembly [14]
	Clogged external filter	Replace external filter
	Overflow protection device is shut off	Check(Reset float)/Replace Overflow protection device
	Loose or incorrect set-up	Set-up unit correctly without any leak.
	Aspirant draw into unit	Follow your facilities procedures for handling contaminated products. (DO NOT SEND UNIT BACK TO THE MANUFACTURER)
Gauge doesn't respond to changes in suction	Gauge assembly is not properly aligned.	Ensure gauge assembly [8] is properly aligned.
	Missing/Damaged O-Rings	Replace O-Rings [13]
	Gauge assembly is damaged	Replace gauge assembly [8]
	Digital Unit Only: Depleted batteries	Digital Unit Only: Replaced Gauge [8]/Batteries
Suction level cannot be adjusted	Unable to push and rotate knob	Push and rotate knob [3] if stuck Replace actuator [10], drive gear [7], Regulator Case [6], OTS assembly [11].
	Damaged OTS assembly	Replace OTS assembly [11]
	Regulator module is stuck in full OFF or full ON position	Rotate the knob [3] to free the Regulator Module Assembly [14]
	Snap cap separated from regulator module housing.	Reassemble snap cap [15] onto regulator module housing [21] Replace snap cap [15] and/or regulator module housing [21] Replace Regulator Module Assembly [14]
	Damaged/Missing spring inside regulator module assembly	Replace Regulator module assembly [14]
	Damaged/Missing O-ring, Quad-ring on regulator module	Replace O-ring [22] and/or Quad-ring [23]
	Damaged Diaphragm inside regulator module	Replace Diaphragm [17] or regulator module assembly [14]
	Damaged Regulator Module Assembly	Replace Regulator module assembly [14]

5/Troubleshooting

SYMPTOM	POSSIBLE CAUSES	POSSIBLE SOLUTION
Erratic gauge movement resulting from regulator adjustment	Damaged Diaphragm inside regulator module	Replace Diaphragm [17] or regulator module assembly [14]
	Damaged/Missing O-ring, Quad-ring on regulator module	Replace O-ring [22] and/or Quad-ring [23]
	Gauge assembly is damaged	Replace gauge assembly [8]
Knob stuck in full OFF or full ON position	Excessive force applied	Rotate the knob [3] to free the Regulator Module Assembly [14]
Suction level can be adjusted without pushing the knob in	Damaged drive gear	Replace drive gear [7]
	Damaged actuator	Replace actuator occlude-to-set [10]
	Damaged Knob	Replace knob [3]
Gauge won't zero	Damaged gauge assembly	Replace gauge assembly [8]
Unit fails to cycle properly in INT mode	INT mode not selected	Turn selector switch [34] to INT position
	Timing Module Assembly not assemble correctly	Assemble Timing Module Assembly [24] as shown in diagram.
	Damaged Selector switch	Replace Selector switch [34]
	Damaged Selector switch	Replace Selector switch [34]
	Missing O-ring on timing module assembly	Replace O-ring [13] on Timing Module Assembly [24]
	Flow control valve is fully in	Adjust Flow control valve [28].
	Evidence of Aspirant on patient port of Timing Module Assembly (other side of flow control valve)	Unit is contaminated - Follow your facilities procedures for handling contaminated products. (DO NOT SEND UNIT BACK TO THE MANUFACTURER)
	Timing Module Assembly adjusted incorrectly	Adjust/Replace timing on timing module assembly [24] as shown in section 9.1.
	Damaged Timing Module Assembly	Replace Timing Module Assembly [24]
	Damaged manifold Assembly	Replace manifold assembly [35]
Whistling/buzzing noise from the unit	Need to apply grease on stem on regulator module	Apply grease on stem [18]
Gauge responds slowly to changes in suction/failed bleed down test	Blocked bleed hole orifice	Clean bleed hole orifice [32]
	Damaged gauge assembly	Replace gauge assembly [8]
	Damaged/Clogged Supply side or Patient side fittings	Replace fittings if damaged/clogged Retighten/Torque if found loose
Vacuum relief valve activates below specified range {PED and NEO ONLY}	Damaged regulator case	Replace regulator case [6]
	Damaged diaphragm	Replace diaphragm [17]
	Damaged/loose set screw	Replace/Adjust set screw 8700-0007-400.
	Damaged vacuum relief assembly	Replace vacuum relief assembly 6700-0045-700.
Vacuum relief valve does not activate at specified range {PED and NEO ONLY}	Damaged vacuum relief assembly	Replace vacuum relief assembly and follow section 7.5 suction level limit setting.

Note: [ ] indicate item number for reference from page 20.

6.1 Service Tools and Equipment

CAUTION: Use of lubricants other than recommended, may degrade plastic or rubber components.

The following items should be on hand during any service procedure:

- Supply Vacuum: 500 mmHg (66.7 kPa) minimum and 80 LPM open air flow minimum
- Phillips-head screwdriver, No. 2
- Flat-head screwdriver, 1/4 inch
- Phillips-head screwdriver, No. 1
- Open-end adjustable wrench
- Wooden toothpick (O-ring remover)
- Tweezers (Filter remover)
- Tubing clamp
- 1500 mL suction canister with lid
- Bubble leak tester
- Ball Vac Kote® 37951M or equivalent
- Dow Corning® 111 grease (Ohio Medical P/N 6700-0074-200)
- Loctite® 242 removable thread locker (Ohio Medical P/N 0220-5016-300)
- Stop watch or VACUTIMER (Ohio Medical P/N 6700-0438-800)
- Vacuum Calibration Gauge, zero to full wall vacuum range (0-760 mmHg/0-101.3 kPa), recommend Dwyer® Series DPG-100 Digital Pressure Gauge or equivalent (Dwyer Instruments, Inc., 219-879-8000)
- 50 L/min Flowmeter, 6-50 L/min scale, recommend Dwyer VFA-26 or equivalent (Dwyer Instruments)
- 10 L/min Flowmeter, 1-10 L/min scale, recommend Dwyer VFB-66 or equivalent (Dwyer Instruments)

6.2 PTS-ISU

6.2.1 Disassembly

WARNING: If the vacuum regulator is repaired or disassembled in any manner, the service checkout procedure must be performed before using the equipment on a patient.

WARNING: To reduce service personnel exposure to hazardous contamination, clean and disinfect all suction equipment before disassembly.

CAUTION: The gauge assembly must be handled with utmost care. Do not rest the gauge on its face.

Note: See Section 9.1 Illustrated Parts

1. Remove the four case screws from the back of the unit.
2. Holding the unit face-up, carefully pull the case and knob assembly off the backplate. Remove, clean, and/or replace the cover strip.
3. To remove the gauge assembly and foam, grasp gauge and pull straight out. Lubricate or change the gauge O-rings if needed.
4. Remove actuator and Push-To-Set™ assembly.
5. To remove the regulator module, grasp the stud and rotate clockwise.

Note: To disassemble the regulator module, refer to Section 6.3 Regulator Module.

6. Remove the Unilogic module by removing the 2 deep center side screws (No. 1 Phillips). Remove and check beige filter, green filter and seven O-rings. Replace filters if needed. Replace or lubricate O-rings if needed.
7. If needed, remove the timing valve and the flow control valve with a flat-head screwdriver. Replace or lubricate the O-rings if needed.
8. Remove the detent plate and the mode selector switch.
9. Remove the gauge bleed hole filter from the manifold assembly. Replace if needed.
10. Grasp the positive pressure relief valve, and pull from the manifold assembly. Replace if torn or damaged.
11. If needed, remove the faceplate as follows:
    a. Carefully peel back and remove label from the knob.
    b. Disconnect the knob from the drive gear by grasping the knob to remove the knob screw.
    c. Rotate the faceplate collar counter-clockwise to remove.
    d. Remove the faceplate.
12. Grab pull-tab on vacuum relief plug (or vacuum relief valve on PED/NEO units) and pull to remove. Replace if damaged.

6.2.2 Assembly

CAUTION: To prevent stripping the plastic case threads, place the manifold screws in the holes and turn counter-clockwise until it drops into the original threads, then tighten the screws.

1. Before assembly, lubricate all O-rings and the rubber surface on the inside of the mode selector switch with a small amount of Dow Corning® 111 Valve Lubricant & Sealant, or equivalent.

2. Place the gauge bleed hole filter in its proper location.
3. Install the positive pressure relief valve and the vacuum relief plug (or vacuum relief valve on PED/NEO units).
4. Unilogic Module Assembly
    a. Install the beige and green filters in the Unilogic module.
    b. Install the seven O-rings on the posts of the Unilogic module.
    c. If removed during disassembly, install the timing valves and/or flow control valve. Rotate each clockwise about 3 turns from thread engagement.
5. Mode Selector Switch Assembly
    a. Place the mode selector switch on the manifold assembly with the rubberized side down.
    b. Place the detent plate on the manifold assembly with the detent fingers facing down.
    c. Install the Unilogic module. Push down until all posts and O-rings are seated into manifold assembly. Firmly tighten the two small screws to maximum torque of 4 in-lbs (0.45 N-m).
    d. After tightening the screws, test that the mode selector switch's movement is firm. Do not over tighten the screws.
6. Install the regulator module assembly by placing it in the manifold and turning counter-clockwise. Rotate the module so that the flat sides of the stud are vertical.
7. Install Push-To-Set™ assembly in the manifold.
8. Position the actuator on the Unilogic module over the regulator module assembly and resting on the Push-To-Set™ assembly.
9. Gauge Assembly
    a. Place one O-ring on the gauge post on the Unilogic module assembly.
    b. Insert one O-ring into the gauge orifice. Ensure O-ring is flush with the back of the gauge.
    c. Attach the foam to the back of the gauge with the short leg at the six o'clock position. Place the gauge assembly on the gauge post on the Unilogic module assembly and press down firmly. Ensure the gauge assembly is properly aligned.
10. Case Assembly
    a. With the case facing up, place the faceplate on the case.
    b. Attach the faceplace collar by placing it on the faceplate around the knob stem. Rotate clockwise to tighten.
    c. Place the drive gear inside the knob stem in the back of the case.
    d. Place the knob on top of the drive gear on the front of the case and rotate the knob until its keys align with the drive gear.
    e. Place the screw in the center of the knob and tighten to fasten the drive gear to the knob.
    f. Place the label on the knob.
    g. With the unit facing up, place the case assembly on top of the unit.
    h. Install and tighten the four screws in the back of the unit.
11. Install adapters/probes and fittings.

Note: For proper installation of adapters/probes and fittings, see Section 8.6 Installation Procedure for Adapters/Probes and Fittings.

6.3 Regulator Module

Note: See Section 9.1 Illustrated Parts

CAUTION: Do not lubricate any internal components of the regulator module assembly.

6.3.1 Disassembly

1. Remove the quad-ring from the piston stem and the O-ring from the housing. Lubricate or replace if needed.
2. Lift and pull tabs to pry off and remove the cap.
3. Peel the diaphragm from the piston head.
4. With the piston head facing down, lift the housing to separate.
5. Remove springs from the piston stem.

6.3.2 Assembly

1. With the piston head facing down, place the springs on the piston stem.
2. Place the housing over the piston and slide the piston stem into the housing.
3. Place the quad-ring on the tip of the piston stem.
4. Place the O-ring on the housing.

5. Fold the diaphragm and place it on the piston head.
6. Place the cap on the housing and press until it snaps into place.

6.4 Digital Gauge

Important: BATTERY LOW INDICATOR: When a battery icon appears on the gauge it indicates that the battery is low. Please take the unit out of service immediately and contact an Ohio Medical Customer Service Representative for battery replacement.

Important: If the low battery condition is not addressed and the battery becomes fully depleted, the gauge will not show any readout, including the low battery icon or gauge pressure. If the gauge were to go blank during suctioning, the unit will continue to suction and the intermittent feature will continue to operate. Once completing that procedure, it is important to immediately take the unit out of service and contact an Ohio Medical Customer Service Representative for battery replacement.

Note: Both batteries are positioned with the positive side facing up relative to the display.

6.4.1 Removal of Batteries

1. Remove digital gauge as described in Section 7.2.1 Disassembly.
2. Using a flat-head screwdriver, push batteries out at a 45° angle.

6.4.2 Inserting Batteries

1. Place negative side of battery into battery slot (battery will be at an angle).
2. Using a flat-head screwdriver, gently push in positive battery contact while sliding battery in place.

6.5 Suction Level Limit Setting
(PED and NEO Models ONLY)

⚠ **WARNING: This Low Vacuum Limit Setting Procedure must be followed when repairing Low Vacuum Regulators. Failure to do this may result in suction exceeding the prescribed level.**

6.5.1 Vacuum Relief Valve Adjustment

1. Remove the cover (see Section 6.2.1 Disassembly).
2. Connect the supply vacuum to the adapter/probe port.
3. Connect an external vacuum test gauge to the patient port.
4. Move the mode selector switch to | (CONT).
5. Slowly rotate the regulator module to increase the vacuum level. Note the suction level at which the relief valve opens. The relief valve should open at 140 mmHg ± 5 mmHg (18.7 kPa ± 0.7 kPa) on the external test gauge.
6. If adjustment is required, grip the vacuum relief valve firmly with pliers and rotate the screw about 1/8 turn with a screwdriver. Repeat the previous step and check the suction level at which the valve opens.

Note: Clockwise rotation will increase the suction level at which the relief valve opens. Counter-clockwise rotation will decrease it.

7. Lock the adjusting screw with a drop of removable thread locker such as Loctite 242. Repeat step 5 to verify the vacuum relief valve setting.
8. Re-attach the cover (see Section 6.2.2 Assembly).

WARNING: Excess Loctite® may seal the steel ball to the seat. This will disable the vacuum relief valve and may allow suction to exceed the preset limit.

CAUTION: When Loctite is used on the vacuum relief safety valve, ensure that it only contacts the metal parts. Loctite causes many plastic parts to deteriorate.

6.5.2 Vacuum Limiting Set Screw Adjustment

6.5.2.1 Pediatric Unit

1. Adjust the regulator until the unit's gauge reads 135 mmHg (18.0 kPa).
2. Rotate the set screw located above the regulator knob clockwise until it stops against the regulator module and then place one drop of Loctite 242 onto the set screw.
3. Turn the regulator counter-clockwise then clockwise until it stops against the set screw. Ensure that the gauge reads 135 mmHg ± 5 mmHg (18.0 kPa ± 0.7 kPa) and that the relief valve does not activate. For the digital unit, ensure that the gauge reads 135 mmHg ± 2 mmHg (18.0 kPa ± 0.3 kPa).

6.5.2.2 Neonatal Unit

1. Adjust the regulator until the unit's gauge reads 100 mmHg (13.3 kPa).
2. Rotate the set screw located above the regulator knob clockwise until it stops against the regulator module and then place one drop of Loctite 242 onto the set screw.
3. Turn the regulator counter-clockwise then clockwise until it stops against the set screw. Ensure that the gauge reads 100 mmHg ± 5 mmHg (13.3 kPa ± 0.7 kPa) and that the relief valve does not activate. For the digital unit, ensure that the gauge reads between 99 mmHg and FULL (13.2 kPa and FULL).

7.1 Setup

1. Verify there is 500 mmHg ± 10 mmHg (66.7 kPa ± 1.3 kPa) vacuum on the supply gauge.
2. The supply open flow must be 80 LPM minimum.
3. Connect the supply vacuum to the adapter/probe port.

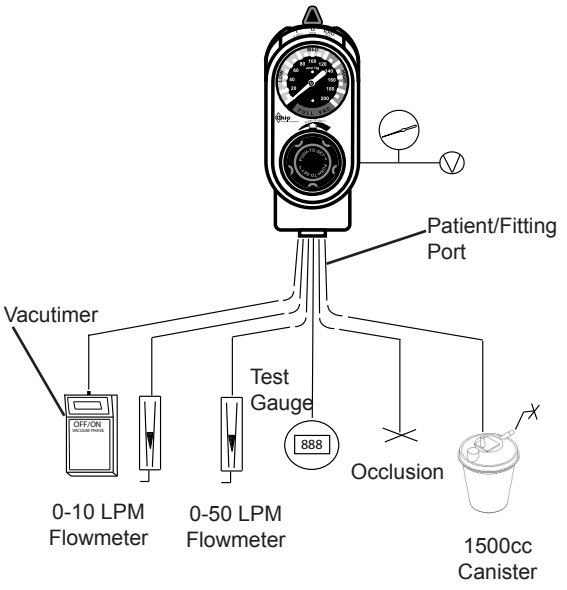


Figure 9: Service Checkout Procedure Setup

7.2 Push-To-Set™ Test

1. Connect the 10 LPM flowmeter to the patient port.
2. Move the mode selector switch to | (CONT).
3. Set 200 mmHg (26.6 kPa) on the gauge and keep the knob pushed in. For the pediatric unit set at 135 mmHg (18.0 kPa) and for the neonatal unit set at 100 mmHg (13.3 kPa).
4. Make certain leakage at the patient port connection is no more than 1 LPM.
5. While observing the flowmeter with the knob still pushed in, rotate the knob. Leakage should be no more than 1 LPM. Release the knob and move the mode selector switch to O (OFF).

7.3 Gauge Test

Note: Analog gauges are supplied with an accuracy of ±5% of full scale deflection throughout their range. See step 4 of Section 7.7 Regulation Test.

Note: Digital gauges are supplied with an accuracy of ±1% of full range at 22°C.

Note: All gauge needles should come to rest within the zero range bracket or return to the stop pin when no suction is being supplied. Gauges which do not comply may be out of calibration. Digital gauge should read "0" when no suction is applied. No calibration required on digital gauges.

Note: When checking the accuracy of the gauge on the analog unit, be sure that the calibration gauge has an accuracy of 1% of full scale deflection or better.

1. Connect the regulator's fitting/patient port to the low calibration gauge with tubing.
2. Move the mode selector switch to | (CONT).
3. Ensure that the gauge is in agreement with the low vacuum calibration gauge within ±10 mmHg (± 1.3 kPa) for the adult model. For the PED/NEO models, ensure that the calibration gauge is within ±8 mmHg (± 1.1 kPa). Recommended test points are 40 and 80 mmHg (5.3 and 10.7 kPa) for the adult/PED/NEO models and 140 mmHg (18.7 kPa) for the adult model only.
4. Adult model ONLY: Push and rotate the suction control knob fully clockwise. Ensure that the vacuum calibration gauge reads at least 450 mmHg (60.0 kPa) and that the gauge on the unit is in the FULL VAC range.
5. For the adult model ONLY: Move the mode selector switch to |O|O (INT) and ensure that the vacuum calibration gauge reads at least 400 mmHg (53.3 kPa).
6. Push and rotate the suction control knob fully counter-clockwise (decrease) and verify the gauge reading decreases to zero.

7.4 Leak Test

7.4.1 Supply Side

1. Connect the adapter/probe port to port “A” of the bubble leak tester. Allow the fitting/patient port to be open to air.
2. Move the mode selector switch to O (OFF).
3. Connect port “B” of the bubble leak tester to the supply vacuum regulated to 500 mmHg (66.7 kPa).
4. Wait 20 seconds. No more than 6 bubbles should appear in the next ten seconds.

Prior to venting port “A” of the bubble leak tester to atmosphere (i.e. turning the supply regulator off), ensure the tubing from port “B” has been disconnected from the adapter/probe port of the vacuum regulator.

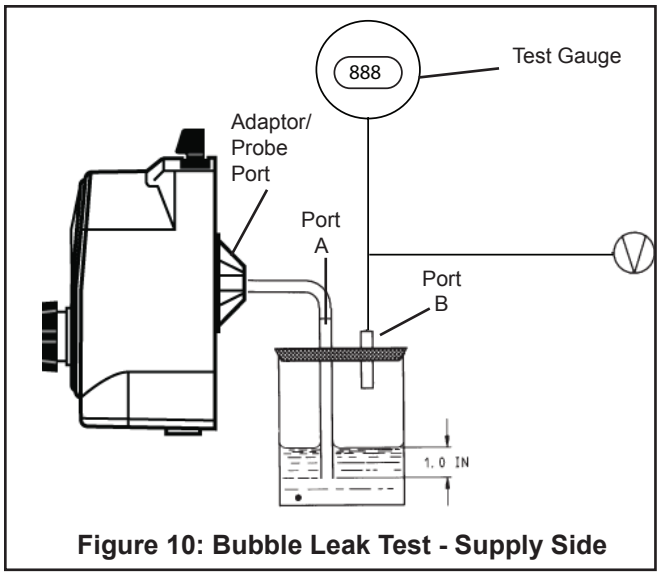


Figure 10: Bubble Leak Test - Supply Side

7.4.2 Patient Side

1. Connect the supply vacuum tubing to the adapter/probe port.
2. Connect the fitting/patient port to port “A” of the bubble leak tester with tubing. Allow port “B” of the bubble leak tester to be open to air.
3. Rotate the suction control knob a minimum of one full turn clockwise (increase). No bubbles should appear in the next ten seconds.
4. Rotate the suction control knob fully counter-clockwise (decrease).
5. Move the mode selector switch to | (CONT). No bubbles should appear in the next ten seconds.

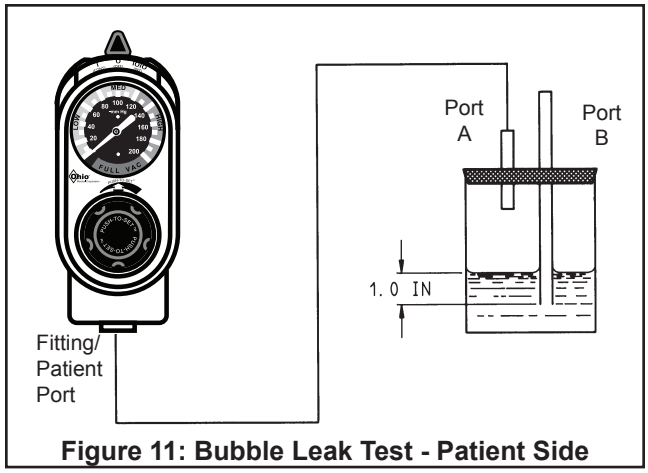


Figure 11: Bubble Leak Test - Patient Side

7.5 Flow Test

Note: All PTS-ISU models should produce a minimum of 25 LPM from the patient port given the following conditions:

- The supply open flow is 80 LPM minimum.
- The supply vacuum pressure is 500 mmHg ± 10 mmHg.
- The unit has fittings on the fitting/patient and adapter/probe ports with minimum inner diameters of 0.140”.
- The unit is either directly connected to the vacuum source, or connected with a tube no more than 4” in length with a minimum inner diameter of 0.25”.
- The unit is connected to a flowmeter with a tube no more than 4” in length with a minimum inner diameter of 0.25”.
- The unit is set to 100 mmHg ± 5 mmHg (12.7 kPa ± 0.7 kPa) in | (CONT) mode.
- Adult models ONLY: the unit should produce a minimum of 40 LPM at maximum vacuum in | (CONT) mode.

7.5.1 Continuous Mode Flow Test

1. Connect the fitting/patient port to the 50 LPM flowmeter.
2. Move the mode selector switch to | (CONT).
3. Set the unit to 100 mmHg ± 5 mmHg (12.7 kPa ± 0.7 kPa).
4. Release the suction control knob and verify that the flow rate exceeds 25 LPM.
5. Adult models ONLY: Push and rotate the suction control knob fully clockwise.
6. Release the suction control knob and verify that the flow rate exceeds 40 LPM.

7.5.2 Intermittent Mode Flow Test

1. Remove the faceplate (see Section 6.2.1 Disassembly).
2. Use a flat-head screwdriver to rotate the flow control valve two turns counter-clockwise from its seat.
3. Move the mode selector switch to | (CONT).
4. Set 120 mmHg (16.0 kPa) on the regulator gauge (100 mmHg (13.3 kPa) for PED and 80 mmHg (10.7 kPa) for NEO).
5. Connect the regulator fitting/patient port to the 10 LPM flowmeter.
6. Move the mode selector switch to |O|O (INT).
7. During the “ON” cycle, adjust the intermittent flow rate to 8 LPM ± 1 LPM. To increase the flow rate turn the valve counter-clockwise. To decrease the flow rate turn the valve clockwise.

7.6 Timing Cycle Adjustment

WARNING: If the timing valves are turned all the way clockwise, the PTS-ISU will not cycle.

Factory Settings:

“ON” Cycle: 15 seconds ± 3 seconds
“OFF” Cycle: 8 seconds ± 3 seconds

To set the timing cycles, perform the following procedure.

Note: Please have a stop watch or a Vacutimer on hand to measure the length of the timing cycles.

1. Rotate the collar which is located directly behind the suction control knob counter-clockwise until loose (Figure 12).
2. Unhook the faceplate by pulling it forward until it is loose and rotates downward (Figure 13).

Figure 12 **Figure 13**

3. Occlude the fitting/patient port by inserting a plug or clamping the tubing or connecting a Vacutimer to fitting/patient port.(See Figure 9)
4. Move the selector switch to | (CONT).
5. Set 120 mmHg (16.0 kPa) on the regulator gauge for the adult model. For the pediatric model, set the regulator gauge to 100 mmHg (13.3 kPa) and for the neonatal model, set the regulator gauge to 80 mmHg (10.7 kPa).
6. Move the mode selector switch to |O|O (INT) with the fitting/patient port still occluded.
7. Wait 20 seconds. If the regulator does not cycle "OFF" within 20 seconds, use a flat-head screwdriver to rotate the "ON" timing valve stem counter-clockwise and continue rotating until the unit cycles "OFF" (Figure 14).

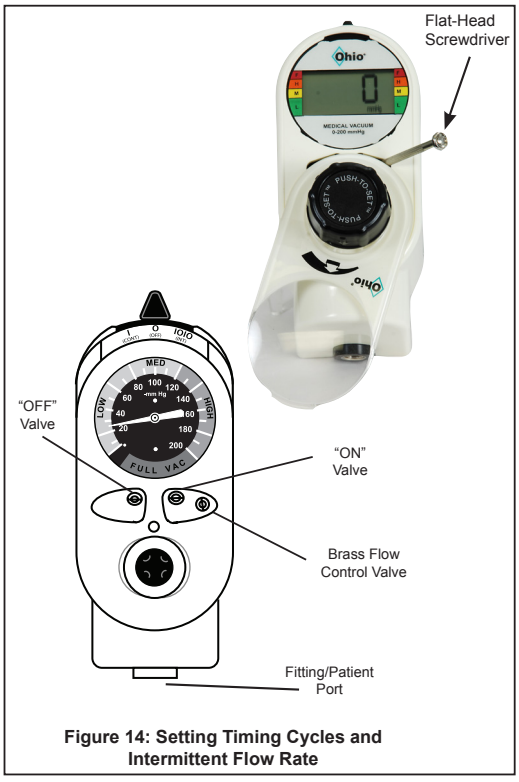


Figure 14: Setting Timing Cycles and Intermittent Flow Rate

8. Wait 20 seconds. If the regulator does not cycle "ON" within 20 seconds, use a flat-head screwdriver to rotate the "OFF" timing valve stem counter-clockwise and continue rotating until the unit cycles "ON".
9. Once the regulator has completed an “ON” and “OFF” cycle, fine tune each cycle to the desired time by adjusting the corresponding valve. To increase the time, turn the timing valve stem clockwise. To decrease the time, turn the timing valve stem counter-clockwise.

Note: Start by using half turn increments to adjust the timing. As the target time is approached, use finer adjustments, e.g., 1/8 turn, to reach the desired timing.

10. Re-attach the faceplace by rotating it upward and snapping it in place.
11. Tighten the collar (located behind the suction control knob) by rotating it clockwise to tighten.

7.7 Regulation Test

1. Remove any equipment attached to the patient port.
2. Set the unit to 100 mmHg (13.3 kPa).
3. Open and close the fitting/patient port several times to create various flow rates through the regulator.
4. With the fitting/patient port occluded, the gauge should return to the setting listed in step 2 within the following tolerances:
   - For analog units, the gauge should return to ± 10 mmHg (± 1.3 kPa) for the adult model and ± 8 mmHg (± 1.1 kPa) for the PED/NEO models.
   - For digital units, the gauge should return to ± 2 mmHg (± 0.3 kPa) for the adult/PED models and ± 1 mmHg (± 0.1 kPa) for the NEO model.

7.8 Vacuum Build-up/Bleed-down Test

7.8.1 Intermittent Mode

1. Move the mode selector switch to |O|O (INT).
2. Connect the regulator fitting/patient port to the 1500 mL suction canister with lid.
3. Set 120 mmHg (16.0 kPa) on the regulator gauge for the adult model. For the pediatric model, set the regulator gauge to 100 mmHg (13.3 kPa) and for the neonatal model, set the regulator gauge to 80 mmHg (10.7 kPa).
4. During the “ON” cycle, check that the suction increases to the preset 120 mmHg (16.0 kPa) for the adult model, 100 mmHg (13.3 kPa) for the pediatric model, and 80 mmHg (10.7 kPa) for the neonatal model within 5 seconds or less on the regulator gauge.
5. During the “OFF” cycle, check that the suction decreases to zero on the regulator gauge (zero stop pin for analog gauge) within 5 seconds.
6. If the regulator fails either the build-up or bleed-down test, replace the regulator module.

7.8.2 Continuous Mode

1. Move the mode selector switch to | (CONT).
2. Set 120 mmHg (16.0 kPa) on the regulator gauge for the adult model. For the pediatric model, set the regulator gauge to 100 mmHg (13.3 kPa) and for the neonatal model, set the regulator gauge to 80 mmHg (10.7 kPa).
3. Move the mode selector switch to O (OFF) and observe the gauge. Check that the suction decreases to zero on the regulator gauge (zero stop pin for analog gauge) within 10 seconds.

8.1 General Maintenance of Suction Equipment

WARNING: The Pre-use Checkout Procedure must be performed before using this equipment on each patient. If the regulator fails any part of the Pre-use Checkout Procedure, it must be removed from service and repaired by qualified service personnel.

WARNING: If the unit has been contaminated, clean and disinfect all suction equipment before disassembly.

PTS-ISU should be kept in use or used on a rotating basis. Internal parts of unused equipment may tend to deteriorate.

Maintenance of the vacuum piping system is as important as maintenance of the suction equipment. The use of collection canisters with reliable shut-off valves, overflow safety trap assemblies and disposable suction filters will protect the regulator, wall outlet, and piping system. The flow rate at the wall outlet should be checked on a yearly basis and suitable cleaning of the outlets should be performed as needed. The flow rate measurement should meet NFPA®99 and/or ISO® standards.

Routine maintenance and inspection are important to the performance of suction equipment. The following is a recommended list for care of suction equipment after each patient use.

1. Keep connecting tubing, fittings and adapters/probes clean.
2. Wipe all exterior surfaces with a solution of water and mild detergent or approved cleaning solutions.
3. Perform a careful visual inspection of the vacuum regulator.
4. Check that the high flow disposable suction filter is clean and in good condition.

5. Check that all tubing is in good condition and connected securely to the correct ports.
6. Check the floats in the Overflow Protection Device and collection canister for correct operation.
7. Perform the Pre-use Checkout Procedure.

8.2 Recommended Maintenance Schedule

We recommend the following to determine the maintenance schedule appropriate for each facility:

1. Periodically (as required, but no less than annually) inspect the overall condition of the vacuum regulator. Test gauge accuracy (Section 7.3 Gauge Test) and perform the pre-use checkout procedure (See PTS-ISU Instrucitons for Use for the Pre-use Checkout Procedure). If the regulator does not pass, refer to troubleshooting (Section 5 Troubleshooting).
2. Determine a maintenance schedule based on data from your periodic inspections. Follow the guidelines below.

8.2.1 Maintenance Schedule

Item	Minimum Frequency	Comments
Service Checkout Procedure	Every 24 months or as required	If the regulator does not pass, refer to troubleshooting (Section 6 Troubleshooting). Repair as needed
Elastomeric parts, O-rings, gaskets, diaphragms, internal filters	As required	Cleaning, lubrication and replacement interval depends on hours of usage and environmental conditions. Replace, lubricate, and repair as needed

8.3 Repair Policy

WARNING: To reduce transportation personnel and/or service personnel exposure to hazardous contamination, clean and disinfect all suction equipment before shipping for service.

CAUTION: Do not steam autoclave or liquid sterilize the PTS-ISU. Severe impairment to the operation of the regulator will result. The only acceptable method of sterilization is with gas (ethylene oxide).

CAUTION: Only competent individuals trained in the repair of this equipment should attempt service.

Do not use malfunctioning equipment. Make all necessary repairs. Have the equipment repaired by qualified service personnel or by Ohio Medical. After repair, perform the Service Checkout Procedure to ensure that the product is functioning properly, and complies with the manufacturer's published specifications.

8.4 Technical Assistance

If technical assistance is required, contact Ohio Medical technical support at +1 857-855-0500 or toll free at 866-549-6446.

8.5 Return Instructions

1. Clean and disinfect the vacuum regulator.
2. Package securely for protection, preferably in the original container.
3. Include a letter describing in detail any difficulties experienced with the product. Include the person, title, and telephone number to contact for functional questions.
4. If the vacuum regulator is covered under warranty, include the warranty information that came with the device and a copy of the invoice.
5. Call toll free 866-549-6446 or +1 847-855-0500 and ask customer service for an RMA number to include with your shipment.
6. Ship the vacuum regulator prepaid. Write your return address and billing address information on the package or letter that comes with the package.

   For Warranty and non-warranty repairs, mail the package to

   Ohio Medical Corporation
   1111 Lakeside Drive
   Gurnee, IL 60031 USA
   RMA #_____

   In other locations contact your nearest Ohio Medical office or authorized Ohio Medical distributor.

8.6 Installation Procedure for Adapters/Probes and Fittings

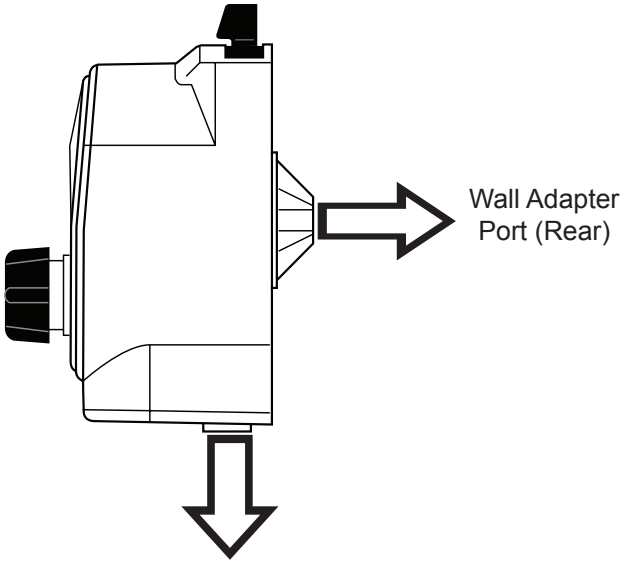
CAUTIONS:

Do not use any Loctite® products or any products which contain Methacrylate Ester as an active ingredient to seal the threads on the adapters/probes and fittings.

All Ohio Medical regulators are supplied with 1/8" NPT female ports. The standard port facilitates simple adaptation to any quick disconnect system. Fittings are available from Ohio Medical to adapt to your quick connect system. We recommend you purchase the appropriate fittings with your regulator at the time of purchase. The fittings will then be factory installed prior to shipping.

In the event that you must assemble or disassemble fittings, please follow these instructions:

1. Prior to installing the fittings wrap the thread with Teflon tape Ohio Medical P/N 6700-1987-800 or equivalent.
2. Apply appropriate torque 4.0 ft-lb (5.4 N-m) minimum to 10.0 ft-lb (13.6 N-m) maximum.
3. Adapters/Probe and fittings which are not keyed for specific orientation, should be torque approximately 6.0 ft-lb (8.1 N-m).
4. Adapters/Probes and fittings that are keyed to specific orientation, must be torque initially to 4.0 ft-lbs (5.4 N-m). Additional torque is applied only until orientation is correct.
5. Make sure wall adapter are installed to specific orientation so that they are mount straight on wall.
6. The regulator is now ready to be place in service on your suction system.

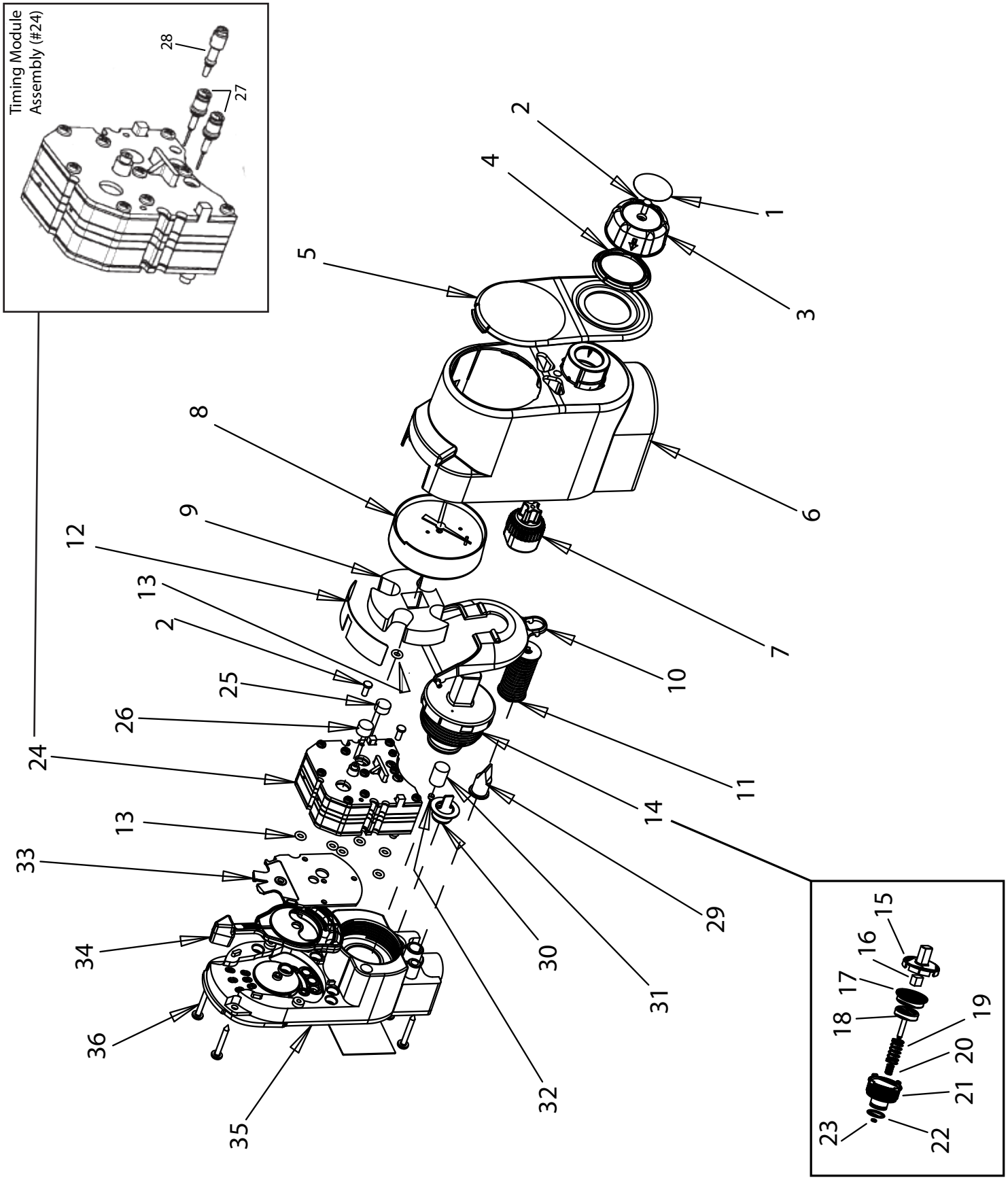


9/Ordering Information

9.1 Illustrated Parts

Item	Part Number	Description	Qty
1.	8700-0005-100	Knob Label	1
2.	6700-0078-400	Knob and Timing Module Screw	3
3.	8700-0017-500	Knob	1
4.	8700-0019-500	Faceplate Collar	1
5.	8700-0014-500 8700-0098-500 8700-0055-500	Faceplate/Adult Faceplate/Neonatal Faceplate/Pediatric	1 1 1
6.	8700-0011-500 8700-0059-500 8700-0060-500 8700-0061-500 8700-0062-500 8700-0063-500 8700-0064-500	Case, Regulator (Analog or Digital, standard) Case, Regulator (Digital, Purple) Case, Regulator (Digital, Red) Case, Regulator (Digital, Blue) Case, Regulator (Digital, Yellow) Case, Regulator (Digital, Lt. Blue) Case, Regulator (Digital, Pink)	1 1 1 1 1 1 1
7.	8700-0021-500	Drive Gear	1
8.	8700-0002-400 VR-DGP-200MM VR-DGP-760MM VR-DGP-100MM VR-DGP-160MM 8700-0020-400 8700-0025-400	ANSI Gauge Assembly, Analog, 0-200 mmHg Gauge Assembly, Digital, 0-200 mmHg Gauge Assembly, Digital, 0-760 mmHg Gauge Assembly, Digital, 0-100 mmHg Gauge Assembly, Digital, 0-160 mmHg ISO Gauge Assembly, Analog, 0-200 mmHg ISO Gauge Assembly, Analog, 0-160 mmHg	1 1 1 1 1 1 1
9.	8700-0047-500	Gauge Mount Foam	1
10.	8700-0015-500	Actuator	1
11.	8700-0002-700	Push-To-Set™ Assembly	1
12.	8700-0038-500	Cover Strip	1
13.	0210-0526-300	O-Ring, 9/32 OD x 5/32 ID x 1/16 W	8
14.	8700-0001-700	Regulator Module Assembly	1
15.	8700-0006-500	Cap	1
16.	8700-0046-500	Cap Plug	1
17.	8700-0008-500	Diaphragm	1
18.	8700-0007-500	Piston with stem	1
19.	8700-0011-400	Spring, 0.475” ID	1
20.	8700-0012-400	Spring, 0.246” ID	1
21.	8700-0005-500	Housing	1
22.	8700-0023-500	O-Ring, -018 Nitrile	1
23.	8700-0024-500	Quad-Ring, -006 Nitrile	1
24.	8700-0004-700	Unilogic Module Assembly (with valves)	1
25.	0221-5879-300	Filter, Green	1
26.	0221-5880-300	Filter, Beige	1
27.	8700-0006-700	Timing Valve	2
28.	8700-0007-700	Flow Control valve	1
29.	6700-0115-400	Positive Pressure Relief Valve	1
30.	8700-0039-500	Vacuum Relief Plug	1
31.	0206-5159-300	Bleed Hole Filter	1
32.	6700-0121-400	Bleed Hole Orifice	1
33.	8700-0040-500	Detent Plate	1
34.	8700-0130-500	Mode Selector Switch	1
35.	8700-0003-700	Manifold Assembly	1
36.	6700-0151-400	Manifold Screw	4
	8700-0001-000	PTS-ISU Service Manual	1

Note: For information on ANSI and/or ISO configurations, fittings, adapters, and accessories, refer to Ohio Medical’s Suction and Oxygen Therapy Product and Accessory Catalog.


Timing Module
Assembly (#24)
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9.2 ACCESSORIES

Description	Part Number		
Disposable Hydrophilic Filter	6730-0350-800 20 Pack	6730-0351-800 200 Pack	
Disposable Hydrophobic Filter Tubing x Tubing nipple	6730-0570-800 3 Pack	6730-0571-800 10 Pack	6730-0572-800 50 Pack
Disposable Hydrophobic Filter 1/8 NPT x Tubing nipple	6730-0580-800 3 Pack	6730-0581-800 10 Pack	6730-0582-800 50 Pack
Tubing	6700-0005-300		

Notes:

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